REMARKS

I. Introduction

With the cancellation without prejudice herein of claims 63, 72, 83 and 96, claims 58-62, 64-71, 73-82, 84-95 and 97 are pending in the present application. In view of the foregoing amendment, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

II. Objections to Specification

The Specification was objected to due to various informalities. Applicant has corrected the Specification as suggested by the Examiner. In addition, Applicant acknowledges that the Preliminary Amendment filed March 11, 2004, should read January 13, 2000, as indicated by the Examiner.

III. Objections to Claims 68, 77, 88, 97

Claims 68, 77, 88 and 97 were objected to due to various informalities. Applicant has corrected the spelling of "inositol" as suggested by the Examiner.

IV. Rejection of Claims 78-97 Under 35 U.S.C. §112

Claims 78-97 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claim 78 has been amended without prejudice herein to recite that "the weight ratio of protein to carbohydrate is not more than about 7 to 1." In addition, claim 79 has been amended without prejudice herein to recite that "the supplement provides about 20 grams of protein and about 3 or more grams of carbohydrates." Also, claim 89 has been amended without prejudice herein to recite that "a dietary supplement comprising about 20 grams of protein, about 3 or more grams of carbohydrates, . . . ". Support for these amendments can be found, for instance, in Example 1 on page 10 of the Specification.

It is therefore respectfully submitted that these claims, and the claims that depend therefrom, fully comply with the requirements of 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is therefore respectfully requested.

V. Rejection of Claims 58-97 Under 35 U.S.C. 103

Claims 58-97[1] were rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of U.S. Patent No. 6,482,448 ("Tabor") in view of U.S. Patent Nos. 6,019,999 ("Miller et al."), 5,550,166 ("Ostlund et al."), and 6,004,926 ("Shimizu et al.")

and U.S. Published Patent Application No. 2001/0041187 ("Hastings et al."). It is respectfully submitted that the combination of Tabor, Miller et al., Ostlund et al., Shimizu et al. and Hastings et al. does not render unpatentable claims 58-97 for at least the following reasons.

Claim 58 relates to a method for supplementing the diet of an athlete. Claim 58 has been amended herein without prejudice to recite that the method includes the step of administering immediately following an exercise period an effective amount of a supplement. Support for this amendment can be found, for instance, at page 9, line 31 – page 10, line 2 of the Specification, which states that "[i]n order to maximize the effects of a food supplement according to the present invention, in enhancing muscle size and/or strength, it is preferred that the food supplement is administered to the diet of the athlete immediately following an exercise period." Claim 58 recites that the supplement includes a source of amino acids and an effective amount of at least one substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, L-arginine, N-acetyl cysteine, glucomannan and folic acid. Claim 58 also recites that the source of amino acids is a protein and the composition further comprises a carbohydrate, wherein the weight ratio of protein to carbohydrate is about 7 to 1.

Claim 69 has been amended herein without prejudice to relate to a method for supplementing the diet of a human to enhance muscle size and/or strength. Support for this amendment can be found, for instance, at page 2, lines 2-3 of the Specification, which states that "the food supplements of the present invention enhance an athlete's muscle size and/or strength." Claim 69 recites that the method includes the step of administering immediately after an exercise period about 28 grams of a dietary supplement comprising about 20 grams of protein, about 3 grams of carbohydrate. Claim 69 has been amended herein without prejudice to recite that the dietary supplement includes a compound which mimics or enhances insulin activity. Support for this amendment can be found, for instance, at page 2, lines 18-20 of the Specification, which states that "the present invention provides a food supplement comprising a substance which enhances and mimics insulin activity." Claim 69 also

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[1] The Office Action states at page 3 that "[c]laims 1-97 are rejected", however, it is assumed that since only claims 58-97 are currently pending, that the rejection was intended to refer to pending claims 58-97 only.

recites that the dietary supplement includes an effective amount of at least one substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, L-arginine, N-acetyl cysteine, glucomannan, and folic acid.

Claim 78 relates to a method for supplementing the diet of an athlete. Claim 78 has been amended herein without prejudice to recite that the method includes the step of administering immediately following an exercise period an effective amount of a supplement. Support for this amendment can be found, for instance, as set forth above. Claim 78 recites that the supplement includes a source of amino acids and an effective amount of at least one substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, L-arginine, N-acetyl cysteine, glucomannan and folic acid, wherein the source of amino acids is a protein and the composition further comprises a carbohydrate. Claim 78 has been amended herein without prejudice to recite that the method includes the step of, wherein the weight ratio of protein to carbohydrate is not more than about 7 to 1. Support for this amendment can be found, for instance, in Example 1 on page 10 of the Specification.

Claim 89 has been amended herein without prejudice to relate to a method for supplementing the diet of a human to enhance muscle size and/or strength. Support for this amendment can be found, for instance, as set forth above. Claim 89 recites that the method includes the step of administering immediately after an exercise period about 28 grams of a dietary supplement comprising about 20 grams of protein, and about 3 or more grams of carbohydrate. Claim 89 has been amended herein without prejudice to recite that the dietary supplement includes a compound which mimics or enhances insulin activity. Support for this amendment can be found, for instance, as set forth above. Claim 89 also recites that the dietary supplement includes and an effective amount of at least one substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, L-arginine, N-acetyl cysteine, glucomannan, and folic acid.

It is respectfully submitted that the combination of Tabor, Miller et al., Ostlund et al., Shimizu et al. and Hastings et al. does not render obvious the present claims because the combination of Tabor, Miller et al., Ostlund et al., Shimizu et al. and

Hastings et al. does not disclose, or even suggest, all of the limitations recited in independent claims 58, 69, 78 and 89. For instance, it is respectfully submitted that the combination of Tabor, Miller et al., Ostlund et al., Shimizu et al. and Hastings et al. fails to disclose, or even suggest, administering immediately following an exercise period a supplement that includes an effective amount of at least one substance which increases nitric oxide production in the body as recited in claims 58 and 78. The Specification states at page 5, lines 22-26 that "[a]ccording to one aspect of the present invention a substance which increases nitric oxide production may act by stimulating insulin levels in the circulation." None of the references cites in the Office Action disclose or suggest that beneficial effects of administering a supplement that includes an effective amount of at least one substance which increases nitric oxide production in the body immediately following an exercise period.

Furthermore, it is respectfully submitted that the combination of Tabor, Miller et al., Ostlund et al., Shimizu et al. and Hastings et al. fails to disclose, or even suggest, enhancing muscle size and/or strength by administering a dietary supplement that includes a compound which mimics or enhances insulin activity as recited in claims 69 and 89. The Specification states at page 3, line 31 – page 4, line 23 that "[t]he food supplements and methods of the present invention may provide further and significant size and strength enhancement through the role of certain substances which mimic and/or increase the sensitivity of insulin, in conjunction with a source of amino acid. . . , increased availability of these GPI precursors, increase insulin sensitive and these GPIs can trigger insulin signalling pathways and events independent of insulin thereby mimicing the effects of insulin . . . and can thereby increase the development of muscle cells. Consequently, supplements which comprise a substance which can enhance and/or mimic insulin activity, and a source of amino acids, preferably any source of protein, more preferably, whey, may provide *further and significant muscle size and strength enhancement as compared with supplements employing only proteins or amino acids*." Emphasis added.

Of the cited references, the Office Action relies only on Ostlund et al. as disclosing a compound that mimics or enhances insulin activity. However, Ostlund et al. purports to relate to pinitol and derivatives thereof for the treatment of metabolic disorders. Specifically, Ostlund et al. state that "[p]initol and derivatives and metabolites thereof are useful in nutritional and medicinal compositions for treating conditions associated with insulin resistance, such as . . . complications arising from athletic activity or inactivity." Ostlund et al. do not provide any guidance as to what is meant by "complications arising from athletic activity or inactivity." Applicant respectfully

maintains that Ostlund et al. do not provide any disclosure or suggestion regarding when, e.g., after an exercise period, to take such compositions, nor do they disclose or suggest that such compositions are suitable for enhancing muscle size and/or strength, but rather only to address undefined "complications arising from exercise activity or inactivity."

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

All remaining claims depend from and therefore include all of the limitations of a respective one of these independent claims, and thus, it is respectfully submitted that the cited combination does not render obvious these dependent claims for at least the same reasons given above in support of the patentability of their respective independent claim. In re Fine, supra (any claim that depends from a non-obvious independent claim is non-obvious).

VI. Fees

Any additional fees or charges required at this time in connection with this application may be charged to Patent and Trademarks Office Deposit Account No. 11-0600.

VII. Conclusion

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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